ATTORNEY DOCKET NO.: 0492611-0315 (MIT 6196)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Griffith-Cima, et al.

Examiner:

D. Naff

Serial No.:

09/008.945

Art Unit:

1651

Filed:

January 20, 1998

For:

TISSUE FORMATION BY INJECTING A CELL-POLYMERIC SOLUTION

THAT GELS IN VIVO

Commissioner of Patents Washington, DC 20231

Sir:

DECLARATION UNDER 37 C.F.R. 1.132

We, Anthony Atala, Linda G. Griffith, Charles A. Vacanti, and Keith T. Paige declare as follows:

- 1. We are the inventors of the subject matter disclosed and claimed in United States patent application Serial No.09/008,945 ('945 application) filed January 20, 1998 and entitled "TISSUE FORMATION BY INJECTING A CELL-POLYMERIC SOLUTION THAT GELS IN VIVO". This application claims priority to United States patent application Serial No. 08/056,140 now issued U.S. Patent No. 5,709,854, by Griffith-Cima et al. entitled "Tissue Formation by Injecting a Cell-Polymeric Solution that Gels In Vivo", filed on April 30, 1993.
- 2. This Declaration is presented for the purpose of removing from consideration by the Examiner an abstract by Atala et al., entitled "Cartilage Cells as a Potential Treatment for Reflux", American Academy of Pediatrics, 1992 Annual Meeting, Section on Urology Program for Scientific Sessions, San Francisco, CA, Saturday, October 10-12, (1992) (Reference "R"). The conference began on October 10, 1992, at which time the above-referenced abstract was

available to the public in this country. The present Declaration is presented in accordance with Ex Parte Magner, 133 USPQ 404 (CCPA 1961) and In re Katz, 455,215 USPQ 14, 18 (CCPA1982) and establishes that the allegedly anticipatory material in Reference R was not invented by another.

- 3. Charles Vacanti and Anthony Atala are two of the inventors on the instant application and are also two of the co-authors of Reference R.
- 4. Alan B. Retik is the third co-author of Reference R. Dr. Retik is not an inventor of the claimed invention and did not make an inventive contribution to the subject matter of Reference R. Dr. Retik was working under the direction of Dr. Atala when he participated in the research which was described in Reference R.
- Linda G. Griffith, Charles A. Vacanti, Keith T. Paige, and Anthony Atala mutually conceived and reduced to practice the invention recited in the claims of the '945 application. Dr. Griffith has changed her name from Griffith-Cima since the parent application was filed.
- 6. All statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patents issued thereon.

| Anthony Atala, M.D. | | |
|---------------------|-------|------|
| | | |
| Date | - | |

| Linda Griffith, Ph.D. | |
|--------------------------|--|
| Date | |
| Charles A. Vacanti, M.D. | |
| Date | |
| Keith T. Paige, M.D. | |
| Date | |
| 3207884_1.DOC | |

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rejection of the appealed claims as indefinite and failing to point out the in-

vention.

[4] The lengthy petition, in effect, meraly expresses disagreement with our view that in the particular circumstances of this case the examiner was correct in holding that the procust ahould be defined by the process of making it. We have carefully considered the petition but are not persuaded thereby that our decision is in error. In respect to the patents which petitioners call to our attention, we point out that what was done during the prosecution of other applications for patent is not controlling here.

The petition has been considered but is denied in respect to making any change in our decision.

Ex parte Magner, Long, Ellis, And Patent Office Board of Appeals GRINBTEAD

Patent issued Apr. 17, 1962 Opinion dated Oct. 25, 1961

PATENTS

 Affidavita — Anticipating references (\$ 12.3)

of inven-

Interference — Originality of tion—In general (\$41.551)

Patentability — Anticipation.—Publications—In general (§ 51.2271)

Publication by three of four inventors of instant application, published less than a year before application filing date, is removed as reference by such three inventors affidavit wherein they state that they are authors of publication, that they are three of four co-inventors of invention claimed in application, that fourth coinventor and themselves mutually participated in contramedives mutually participated in conception, research, and reduction to practice of claimed invention, and that publication was prepared from research records of themselves and fourth coquestion of priority is involved; affidavit sufficiently explains relation of publication to application; any competent evidence convincing to Patent Office may be accepted on question of originality. inventor; explanatory affidavit by fourth coinventor is unnecessary; affidavit un-dar Rule 131 is unnecessary since no

Particular patents — Preparing Ura-nous Tetrafluoride

3,030,175, Magner, Long, Ellis, and Grinstead, Preparation of High Purity UF., claim 18 of application allowed.

cision rejecting appeal. Reversed.

BOLAND A. ANDERSON, Germantown, Md., for applicants. Before Agr, Examiner in Chief, and Behrens and Garron, Acting Examiners in Chief. GASTON, Acting Examiner in Chief. This is an appeal from the final rejection of claim 13 the only claim in the case.

Claim 13 is as follows:

phosphate in an organic solvent-diluent selected from the group consist-ing of benzene, ethyl-benzene, chloro-benzene, tohuene, xylene, kerosene, and carbon tetrachloride to extract the vranium therein, treating the extract phase with an aqueous fluohighly pure uranous tetrafluoride from impure uranium laden solvent extraction process strip solutions and ion exchange process and restri-in-pulp process cluste solutions which are at least 8M in hydrochloric acid, the stops comprising treating said solution with a reducing agent thereby reducing the uranium in said solution to the +4 oxidation state, confacting the solution with an entractant phase comprising about 10 to 70% of tributyl ride solution to precipitate uranous tetrafinoride therefrom, and separating the aranous tetrafluoride from the 13. In a process for preparing phases."

The reference relied on is:

AEC Document DOW-147, Sept. 1, 1956, pp. 8-11

reference are sufficiently described in appellants' brief and the Examiner's Appellants' process and that of the Answer-

Claim 13 stands rejected by the examiner as unpatentable over the DOW-147 publication.

J procedure necessary for removing as a reference DOW-147, a nubication by three of the four inventors of this application, published less than a year before the application filing date. [II] The sole issue in this case is the

Decided Mar. 6, 1962 The three co-autants of the four ionthe front, constituting three of the four joint inventors, have filled an efficient which charters, have filled an efficient which states that they are three of the four co-inventors of the invention claimed in this application. The fourth co-inventor and themselves mutually participated in this case, and the portion of DOW-147 in this case, and the portion of DOW-147 in this case, and the portion of DOW-147 in this case, and the fourth co-inventor hemselves and the fourth co-inventor. Appellants urge that this affidavit is afficient to remove DOW-147 as a redence as to the appealed claim.

Appellants urge that this affidavit is a redence as to the appealed claim.

Appellants urge that this affidavit is a sufficient to remove DOW-147 as a redence as to the applicant of the fourth co-inventor in the actual operation conducted by the applicant and that the publication was the applicant and that the publication was the actual operation conducted by the applicant and that the publication was not be application by another was and have not followed the procedure of Ex parte Layne, supra, in that no inventor has been presented. The article is by three of the four inventor has been presented. The article is by three of the four inventors to the application of the relation of the reation of the relation of the question explanation of the relation of the question and them. We think that the affidavit relation in relation of the question eatisfies this requirement, on the question and eatisfies this requirement. co-authors of the publica-

I. Identity and similarity — Word (2) Similar (\$67.4117) (4) "Glamor Fold" so resembles "Bea. Fold" as to be likely to cause confusi

2. Identity and similarity—How dd mined—In general (\$ 67.4051) Differences between decalcomana Differences between decalcomana marks are immaterial and irrelevandetermination of applicant's rights register its mark. register its mark.

173)

of no concern to applicant.

the mark at that time were small conditions and an abandonment of man nor a basis for cancellation of rectation, although assignee never solonar, it has used mark since assigner mark, it has used mark since assign, on goods intended for similar user which could originate from same sou 4. Abandonment—In general (\$67.0; ment by it of registered mark. dence convincing to the Office may be accepted. There is no reason to doubt the statement of the three joint inventors as to the participation of the fourth inventor as this statement is of no

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The decision of the examiner is

benefit to them.

Trademark opposition No. 89,718
American Beauth Pleat, Inc., agai Judkins Company, application, Se No. 82,238, filed Sept. 28, 1959. Opp.

Trademark cancellation No. 7,467 Judkins Company against Ameri tion sustained.

TRADEMARES

in trade.

3. Cancellation-In general (\$ 67.171) Cancellation—Abandoned mark (f

Since opposer's use of its registry mark, and since confusion is likely.

The mark and since confusion is likely.

The marketing of goods under these milities clear that suplicant, at time on ing of petition to cancel opposer's useration, did not possess any right its mark which it could assert again opposer; accordingly, opposer's runght which applicant may have in right which applicant may have in mark; hence, question whether regimark has been abandoned can tion of originality any competent evi-

mark prior to and at time of assignment; fact that assignor's sales un use of mark camet constitute aband Assignor of trademark was us.

55, 1911 C.D. 384 (1911) (proof of actual duction to practice negates having to rely on ie's filing date for constructive reduction to actice). See also Starr v. Farmer, 1883 D. 34, 23 O.G. 2325 (Sec'y Int. 1883), herein it was held that actual reduction to actice may be better evidence of invention an an application but that "Until that evimoe [the application] is overthrown," id. at I, the applicant need do more than rely on fficient! Lindstrom v. Ames, 37 App. D.C.

In any event, I would remand for determination of Daugherty's right to rely on the te of their application as their priority date for a determination of priority based on the idence of Daugherty's actual reduction to s application filing date.

right; no barrier is created by that section unless another has either actually reduced invention to practice or has constructively filing patent á reduced it to practice application.

3. Interference - Priority (§41.70)

Interference — Reduction to practice — Constructive reduction (§41.755)

cation of article is not constructive reduction Section 102(g) has ever been made by anyone. . Unlike filing of patent application, publito practice of subject matter described in it; therefore, disclosure in publication does not prove that any "invention" within meaning of

4. Patentability — Anticipation — Palents — In general (§51.2211)

Patentability — Anticipation — Publications — In general (\$51.2271)

applicant's own work would negate one year period afforded under Section 102(b) during which inventor is allowed to perfect, develop, and apply for patent on his invention and publish descriptions of it if he wishes. Interpretation of Section 102(a) that would make prior patent or printed publication "prior art" even though disclosure is that of

Court of Customs and Patent Appeals

In re Katz No. 82-521

Patentability — Anticipation — In general (§51.201)

Court of Customs and Patent Appeals — Issues determined — Exparte pat-

Decided Aug. 27, 1982

CCPA treats Section 102(g) rejection that oard of Appeals did not specifically reverse

ent cases (§28.203)

closed to public in manner or form that otherwise would fall under Section 102(a); disclosure to public of one's own work constitutes only when disclosure occurred more than one tion, whatever form of disclosure to public, One's own work is not prior art under year prior to application's date, that is, when disclosure creates one-year time bar, to application under Section 102(b); one's own inven-Section 102(a) even though it has been disbar to grant of patent claiming subject matter so disclosed, or subject matter obvious from it, may not be prior art against oneself, absent statutory bar.

> Section 102(g) embodies principle that to entitled to patent one must be first to have nade invention; however, prior conception of ternion by another does not defeat one's

Interference - Priority (§41.70)

having been affirmed

6. Patentability — Anticipation — Publications — In general (§51.2211)

than one year before appellant's application comes within scope of Section 102(a) only if description is not of appellant's own work. Disclosure of publication that occurred less

*As noted in Tofe v. Winethell, supra at 61, 209 SPQ at 382 n. 10, only abandonurent, suppreson or concealment of the invention are grounds uder \$102(g) for awarding priority de jure to the arty who is not the first inventor de facto. Thus, I isapprove of the view expressed by the board in fagdo v. Peltzer, 212 USPQ 838, 845 (BOPT 981) (on Petition for Restaring)

7. Patentability - Anticipation - Publications — In general (§51.2211)

Authorship of article by itself does not raise presumption of inventorship with respect to subject matter disclosed in article, thus, co---- he commerced to be notinessed.

with the "best mode" requirement of the statute has "no right to make" his claims corresponding to the counts and, therefore, is not entitled to an

a party to an interference who has not complied

award of priority, irrespective of testimony as to inventive acts * *

tors merely from fact of co-apthorship; on other hand, when PTO is aware of printed publication that describes subject matter of content and nature of printed publication, as well as circumstances surrounding its publiarticle may or may not raise substantial question whether applicant is inventor; for example, if author, whether he is applicant or not specifically states that he is describing applicalien, not merely its authorship, must be which it must act in absence of other proof) cant's work, no question at all is raised considered

Although submission of disclaiming affida-vits or declarations by other authors of article that does not tell anything specific about inventorship and that reports on scientific have ended inquiry into whether it can be position.

9. Applicants for patent - In general

- cations — In general (§51.2211)

Application for patent of David Harvey Katz, Serial No. 937,574, division of application, Serial No. 764,586, filed Reb. 3, 1977. From decision rejecting claims 1, 5, 17, and 18, applicant appeals. Reversed; Miller,

John H. Lynn and Grant L. Hubbard, both of Newman Rosah Polif for something

Joseph F. Nakamura and Gerald H. Bjorn

sociate Judges. Markey, Chief Judge, and Rich, Br Miller, and Nies, Associate Judges.

Nies, Judge.

application Serial No. 764,586, filed Febricary 3, 1977, and is entitled to that filing dail. The claims were rejected because of a discription of the subject matter of the invention in a publication dated June 1976, white appellant, however, asserts is a description. It is own work. The board was unpersuaded by appellant's declarations to the of Appeals (board) sustaining rejection of daims 1, 5, 17, and 18, all remaining dair of in application Serial No. 937,574 for 'Indu'den of Immunological Tolerance.' The sub-This appeal is from the decision of 11-Patent and Trademark Office (PTO) Boa on effect and sustained the rejection. We revers 80 jed application is a divisional application of

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Background

In June, 1976, eight months before appe A lant's effective filing date, an article ogaint ored by Nicholas Chiorazzi, Zelig Eshhen and appellant was published in the Proceet (ings of the National Academy of Science, U.S.A., Vol. 73, No. 6, pp. 2091-95. There in no dispute that the article (Chiorazzi et al.) fully describes the claimed invention.

Along with his divisional application, pellant filed a declaration in which he clared that;

matter described and claimed in the United States Patent Application Serial No. 764,586, filed February 3, 1977, entitled, INDUCTION OF IMMUNOLOGICAL
TOLERANCE, which subject matter iodisclosed and claimed in part in the divides sional application with which this declarated. He is the sole inventor of the subject lion is submitted

He is co-author of a report in the proceedings of the National Academy of Sci. Tence, U.S.A., Volume 73, No. 6, Page. 2091-2095, June, 1976, communicated to the National Academy of Science by Albert H. Coons, a member of said Academy, on March 8, 1976, that he is the sole inventor of the subject matter which is disclosed in said publication in the proceedings of the National Academy of Science and disclosed and claimed in the application submitted

claimed invention and is published before application is filed (only date of invention on

-itdaa -8. Patentability — Anticipation — Cations — In general (§51.2211)

work in which applicant and other authors have been engaged in some capacity would showing supporting basis for applicant's reasonably concluded that applicant is sole inventor, they are not required by statute or Rule 132; what is required is reasonable

Patentability - Anticipation - Publi-

face of sworn statements to contrary, from article authored by applicant and students working under applicant's direction and Joint inventorship cannot be inferred, in supervision.

Particular patents — Immunological Tolerance Induction

ance, rejection of claims 1, 5, 17, and 18 Katz, Induction of Immunological

Appeal from Patent and Trademark Office Board of Board of Appeals.

udge, dissenting with opinion.

215 USPQ

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215 USPQ

curred less than one year before appellant's application, the disclosure comes within the scope of §102(a) only if the description is not Since the publication in this case ocof appellant's own work.

is essentially an evidentiary one, namely, the sufficiency of applicant's showing to establish that the subject disclosure was his original work, and his atone. We conclude that appellant's declaration is sufficient in this case to The specific question present in this appeal overcome the rejection.

vention and is published before an application is filed (the only date of invention on which it must act in the absence of other proof), the article may or may not raise a substantial question whether the applicant is the inventor. For example, if the author (whether he is presumption of inventorship with respect to the subject matter disclosed in the article. thorship of an article by itself does not raise a Thus, co-authors may not be presumed to be ship. On the other hand, when the PTO is aware of a printed publication, which describes the subject matter of the claimed inthe applicant or not) specifically states that he is describing the work of the applicant, no question at all is raised. The content and nature of the printed publication, as well as As an initial matter, we hold that aucoinventors merely from the fact of co-authorthe circumstances surrounding its publication not merely its authorship, must be considered

work in which they have all been engaged in some capacity at the Harvard Medical School. It was incumbent, therefore, on appellant to provide a satisfactory showing cle does not tell us anything specific about inventorship, and appellant is only one of three authors who are reporting on scientific which would lead to a reasonable conclusion What we have in this case is ambiguity created by the printed publication. The artihat he is the sole inventor. ³ Such showing can be made under Rule 132, 37 CPR 1.132, which provides:

When any claim of an application is rejected on reference to a *** printed publication **** affidavits or declarations traversing [the reference] * ** may be received.

is an inconsistency in that the subject application and its parent by a sole inventor refer to previous work done by "one of the inventors." While adding to the ambiguity, this statement, which appellant's 'The solicitor notes that in the application, there autorney represents was his error in draftsmanship,

inventor of the subject matter described in the article and claimed herein." This was clear rations would have ended the inquiry, but we do not agree that they are required by the statute or Rule 132. What is required is a "disclaiming affidavits or declarations by the lant's position that he is, in fact, the sole error. Submission of such affidavits or declareasonable showing supporting the basis for The board and the examiner held that other authors are required to support appelthe applicant's position.

application and also that disclosed in the publication of proceedings of the National Academy of Science. We do not view this averment as a mere pro forma restatement of declaration that he is the sole inventor of the subject matter described and claimed in his In this case, appellant reaverred in his the oath in his application.

scientific report who are "involved only with assay and testing features of the invention." appellant's view was shared by his co-authors cated, that is, students working under the direction and supervision of appellant. From such a retaitonship, joint inventorship cannot be inferred in the face of sworn statements to it provides a clear alternative conclusion to the board's inference that their names were As acknowledged by the examiner, the names of individuals may be given as authors of a Appellant's explanation is, thus, consistent not only with the content of the article but Katz." This statement is of significance since on the article because they were coinventors. with the nature of the publication. On the record here, the board should not have engaged in further speculation as to whether but rather should have accepted that Chiorazzi and Eshhar were acting in the capacity indisindents working under the direction and su-pervision of the inventor, Dr. David H.

Thus, we conclude that in view of the totality of circumstances, appellant has made a sofficient showing that the cited publication discloses his invention. Accordingly, we reverse the decision of the board.

Reversed

Miller, Judge, dissenting.

The board correctly held that it is reason-

applied against an application for patent filed by one of the coauthors. In re Facius, 56 CCPA 1348, 408 F.2d 1396, 161 USPQ 294 (1969); In re Mathews, 56 CCPA 1033, 408 F.2d 1393, 161 USPQ 276 (1969); In re Land, 54 CCPA 806, 368 F.2d 866, 151 USPQ 621 (1966). Although all of the latter the board has established a line of cases involving only printed publications. In re Magner, 133 USPQ 404 (1961); In re Seaborg, 131 USPQ 202 (1960); In re Hirschler, 110 printed publication ("Chiorazzi et al.") in question is prior art under 35 USC 102 as ship. This inference is sufficient to justify a determination by the PTO that the reference opinions by this court have involved prior patents issued to different inventive entities, USPQ 384 (1952); In re Layne, 63 USPQ 17 (1943). Such cases are analogous to the instant appeal, and, contrary to appellant's arguments, are consistent.

In Layne, the board agreed with the examiner that an affidavit by the applicant, stating that an article published by another was made with the applicant's consent, was not sufficient to overcome the examiner's rejecion. The board stated:

article, H. Lee Flood, should be furnished to afford complete and satisfactory proof of the identity of the article disclosed in the his information from the deponent. It is our view that this affidavit of the writer of the obtain an affidavil of the writer of the article in the publication that he obtained (I) is stated in the brief that counsel can publication.

* * * |UJnii the affidavit referred to is furnished, the rejection on the publication in the Petroleum Engineer appears proper 'As argued by the Solicitor, this printed publica-tion is also evidence that "the invention was known ar used by others in this county, *** or described in a printed publication in this ** * wountry, before the invention thereof by applicant" under 35 USC 102(a) and, as held by the examiner, is evidence that "before the applicant's invention thereof the invention was made in this country by another," under 35 USC 102(g). The "others" in 102(a) "not thinself" in 102(f), and "another" in 102(g) are terms that serve to distinguish between different indicates that the invention was actually reduced to practice; appellant did not oxotest the examiner's rejection on this basis. In this case, Katz, the applicant, is one inventive entity and his effective date of invention, as the record now stands, is his ion's view of section 102(g), the Katz et al. article application filing date. Collectively, Katz, Chiorazzi, and Eshhar comprise a second inventive entity. See inventive entities. Contrary to the majority, opin-

For this reason, the rejection is affirmed is recommended, however that if a prediction of H. Lee Flood is promptly mitted, the claims be allowed.

63 USPQ at 19. Layne differs from present case in that the inventor in Layne on not named as a occurrent, here, Katz was to

of the named coauthors.

When presented with an examiner's r p. tion wilizing a publication coauthored by applicant and his laboratory assistant, 3 board in Hirschler refused to sustain i rejection in view of the submission of affidavit disclaiming inventorship which is executed by the lab assistant. The board.

credit for having collaborated on the search program under the directions of ω sent appellant, is properly acceptable ω in the article may be considered the work of present appellant. Since the article is not a statutory bar, it is not effective affidavit disclaiming inventorship which is executed by the lab assistant. The board if D [A]n affidavi which points out that affiliation no part in writing the article and not the inventor of the subject matter is scribed in the article, but was merely of as coauthor of the article in order to re as coauthor of the article in order to re reference.

110 USPQ at 387. Here, of course, no disclaiming affidavits filed by the thors and alleged noninventors.

Appellant quotes the following statement the board in Seaborg explaining that a Ru 131 affidavit was unnecessary:

having in mind the possibility that Wa might be a joint inventor. But we won The issue is not one of priority but attrib tion of inventorship, the examiner evident emphasize that the bare fact that Wahl the literary co-author is not evidence joint inventorship.

131 USPQ at 203. This statement is 1A out of context, the board actually concluid

basis for challenging this affidavit. In Ia an affidavit by joint author Wahl staff matter claimed herein. In absence of a adversity of interest there seems to be lit the examiner states on page 4 of his answ that he "has no doubt that Seaborg is t On the question of originality any edence convincing to the Office may b. expled. The evidence here is in the forch that he is not the inventor of the subjof the subject mat sole inventor